REMARKS

In the Office Action mailed June 30, 2004, the Examiner rejected claims 1-19 of the present application. By this Amendment, claims 1, 3, 17-19 have been amended.

35 U.S.C. §112

Claims 3, 4, 7, 17, and 18 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Particularly, in claims 3 and 4, the Examiner stated that there is no antecedent basis for "the pores" and that stating that the receptor is attached to both the surface and the pores of a substrate is confusing. Furthermore, in claim 4, the Examiner stated that there is no antecedent basis for a spherical substrate. Applicant has amended claims 3 and 4 to more clearly define the present invention, and it is believed that claims 3 and 4 now conform to the requirements set forth under §112, second paragraph.

The Examiner also rejected claim 17, stating it recites a method rather than the device of claim 15. Claim 18 was rejected for lacking a detection step, as claim 18 is directed to a method for detecting ligands. Claim 19 was rejected, as the Examiner stated that the language "interfaced" is unclear. Applicant has amended claims 17, 18 and 19 to conform with the requirements set forth under §112, second paragraph.

Double Patenting

Claims 1-6, 9-11 and 15-17 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent

No. 6,171,802 in view of Holmgren et al. (U.S. 5,681,571). The Examiner stated that although the claims are not identical, they are not patentably distinct from each other. In light of the claims as now amended, the application requests that this rejection be withdrawn. As now claimed in Claim 1, the present invention is directed to a ligand detection device wherein a substrate positioned within a liquid crystalline materials forms a receptor-ligand complex. The creation of the receptor-ligand complex creates a detectable change in the characteristics of the liquid crystalline material. The '802 patent does not teach such a device, and the teachings of Holmgren do not suggest these distinguishing characteristics in any way. This combination of art cited by the Examiner simply would not result in the present invention as claimed.

35 U.S.C. §102(e)

Claims 1-6, 8-17 and 19 were rejected under 35 U.S.C. §102(e) as being anticipated by Anderson (U.S. 6,482,517). In forming the rejection, the Examiner stated that Anderson teaches a spherical particle coated with nonlamellar crystalline material including an internal core having a liquid crystalline material, and an external coating of receptor protein. The Examiner further states the nonlamellar crystalline material can be porous or non-porous, and is formed from an organic or inorganic compound, including minerals, or metals such as gold. The Examiner further states that receptor proteins are attached to the external coating through chemical attachment or physical attachment. The Examiner then properly notes that in Anderson, the liquid crystalline material is not used to generate a signal indicative of ligand detection.

Applicant respectfully disagrees with the Examiner's position, and sets forth that claims 1-6, 8-17 and 19 are not anticipated nor made obvious by Anderson either alone or in conjunction with other cited art. For example, as now stated in claim 1 of the present application, the device comprises a substrate having ligand receptors attached thereto, which is positioned within a liquid crystal material. Upon the formation of a receptor-ligand complex, the characteristics of the liquid crystal material are altered in a detectable manner to detect the presence of a ligand. This invention as now claimed clearly distinguishes from Anderson, as Anderson instead is directed to a device for delivery of agents such as pharmaceuticals. A coated particle includes the liquid agent for delivery in the core, and upon removal or deterioration of the exterior coating, the agent is released. The device taught by Anderson simply does not relate to the present invention in any significant way. The present invention employs liquid crystalline material as a mechanism by which the creation of a receptor-ligand complex can be detected. The substrate with receptors that are attached to the substrate, are within but not attached or bound to the liquid crystalline material. Anderson teaches that the liquid material is within the core of the particles, stating the core of the particles can include liquid crystalline material and receptor proteins, which does not relate to the present invention.

In the invention according to the independent claims of the present application, the formation of the receptor-ligand complex produces a signal by interfering with the alignment of the liquid crystalline material and therefore the optical characteristics. The present invention does not teach the capture of the liquid crystalline material into or onto the substrate or coating the substrate with liquid crystalline material. The substrate

particles of the present invention serve to link small quantities of ligand into a complex that is large enough to alter the characteristics of the liquid crystal material in which the complex forms. Therefore, Applicant respectfully requests reconsideration of the rejection under §102(e) in view of Abbott et al.

Claims 1-6, 8-11, and 15-17 have also been rejected under 35 U.S.C. §102(e) as being anticipated by Abbott (U.S. 6,284,197). The Examiner stated that Abbott teaches a device and method for detecting analytes that comprises a substrate, a recognition moiety with a mesogenic layer/liquid crystals oriented on the surface, and an interface between the mesogenic layer and a member selected from the group consisting of gases, liquids, solids, and combinations thereof. Abbott is also stated to teach a method for detecting analytes comprising contacting a recognition moiety with the analyte, which causes the liquid crystals proximate to the recognition moiety to change from a first orientation to a second orientation.

This rejection is respectfully traversed in that the claims as now set forth clearly distinguish from Abbott. According to claim 1 as amended, the present invention is directed to a device comprising a substrate having at least one receptor to bind a ligand. The substrate is positioned within a liquid crystalline material, such that when the receptor binds to a ligand, a receptor-ligand complex is formed, which alters the optical characteristics of the liquid crystal material and allows detection of the ligand. The prior art of Abbott simply does not relate to such a device, and instead is directed to a device which does not use "substantially spherical substrate." Furthermore, Abbott does not teach that the receptor-ligand complex formation forms particles in the bulk liquid crystalline material which alter the alignment of the liquid crystals, as is taught by the

present invention. Rather, Abbott teaches a net difference in the liquid crystal alignment after ligand binds to a solid phase receptor. Therefore, Applicant respectfully requests reconsideration of the rejection under §102(e) in view of Abbott et al.

35 U.S.C. §103(a)

Claims 12-14, 18 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Abbott et al. (U.S. 6,284,197) in view of Tarcha et al. (U.S. 5,252,459). In forming the rejection, the Examiner stated that while Abbott fails to teach that the shape of the substrate is spherical, Tarcha teaches an assay method using solid phase/substrate materials such as chromatographic, bibulous, porous capillary material, fiberglass, cellulose or nylon pad, silicon particles, porous gels, polyacrylamide or polystyrene beads, etc. The Examiner stated that it would have been obvious to one of ordinary skill in the art to configure the shape of the substrate taught by Abbott into spherical shaped beads/ particles "as spherical shaped beads are well known in the art as solid phase supported by the teachings of Tarcha." Furthermore, the Examiner stated that one of ordinary skill in the art would find it obvious to use a substrate with a curved shape such as beads or particles.

Applicant respectfully requests reconsideration of the rejection, and submits that there is no teaching or motivation to combine the spherical particles of Tarcha with the method of detection as taught by Abbott et al. Furthermore, it would not be obvious to one of ordinary skill in the art to make the combination. The present invention is directed to the detection of ligands with high sensitivity, therefore, only small quantities of ligand bound to the receptor are required to generate a signal. Tarcha et al. teach an

indicator reagent, assay method and test kit, wherein an indicator reagent is formed by attaching an organic polymer particle to a binding member. The assay method yields results that can be detected by direct visual observation or instrumentation. (i.e. color changes, etc.) While the indicator reagents of Tarcha et al. teach the use of spherical particles, Tarcha et al. is not directed to a method of detection employing liquid crystals, and there is no teaching in Tarcha to place the spheres attached to a specific binding member into liquid crystals to detect the presence of an analyte. Furthermore, employing the spheres of Tarcha et al. as the substrate in the method as taught by Abbott et al., would not result in the present invention because the detection method in Abbott is not based on physically deforming the orientation of the liquid crystals, as defined by the present invention.

Claim 7 was rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson or Abbott in view or Sahouani et al. (U.S. 6,524,665). Claim 7 is directed to a "lyotrphic chromonic liquid crystalline material." The Examiner stated that Anderson and Abbott fail to teach that the liquid crystalline material is chromonic, however, Sahouani teaches "an alignment structure useful in a liquid crystal display device comprising a substrate having disposed thereon a film of a lyotropic nematic or chromonic liquid crystalline material." Furthermore, the Examiner stated that it would have been obvious to one of ordinary skill in the art to use chromonic lyotropic liquid crystalline material because chromonic molecules show a self-organized surface structure that easily and uniformly orient liquid crystals or non-liquid crystal coatings in planar configuration.

Applicant respectfully submits that there is no teaching or motivation to combine these references, and requests reconsideration of the rejection under §103(a).

Combining the Sahouani reference with either Abbott or Anderson would not result in the device according to claim 7, as neither Anderson nor Abbott teach the use of a receptor attached to a spherical particle that forms a receptor-ligand complex that alters the alignment of the liquid crystals, thereby producing an optical signal.

Several new claims are also submitted herewith, which clearly define over the prior art cited and relied upon by the Examiner. New claims 20 and 21 relate to a device and method wherein an amount of liquid crystalline material is provided, which has initial optical characteristics. Substrate(s) are positioned so as to be moveable within the liquid crystalline material. For reasons as set forth regarding the prior art, this device and method are clearly not taught or made obvious by the prior art. Favorable action on these claims is requested.

Conclusion

Prompt reconsideration of this application and allowance of the claims are requested. If the Examiner should have any question regarding this application or the amendment, a call to Applicant's attorney would be appreciated.

Respectfully submitted,

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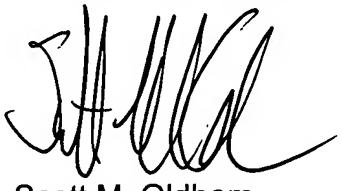
By 

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